



# Department of Public Health and Human Services

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## Industrial Hemp and Cannabidiol Policy for Foods

### Purpose

The purpose of this policy is to address numerous inquiries from entrepreneurs who want to add industrial hemp ingredients or cannabidiol (CBD) to conventional food products or market such products as dietary supplements.

The Montana Department of Public Health and Human Services (DPHHS) has determined that verifiable foodgrade industrial hemp seeds and foodgrade industrial hemp seed oil will be allowed in food, if and only if, the food product is marketed without any and all health and health-related claims. However, CBD is not allowed in food or dietary supplements. Specifically, CBD does not meet the legal definition of an ingredient allowed in dietary supplements because CBD is already regulated as a drug.

### Background

Under the Code of Federal Regulations (CFR), CBD and delta-9 tetrahydrocannabinol (THC) are Schedule One Controlled Substances (21 CFR 1308), and the federal Controlled Substances Act, regulates CBD as a chemical component of the cannabis plant.

According to scientific publications from the National Institutes of Health, CBD has drug properties, and has been scientifically shown to have analgesic, anticonvulsant, muscle relaxant, anxiolytic, neuroprotective, anti-oxidant, and anti-psychotic activity. Also, the federal Food and Drug Administration (FDA) considers nearly all CBD products unapproved drugs. On June 25, 2018, FDA announced approval of CBD as the active ingredient in a drug to treat two rare and severe forms of epilepsy. Therefore, CBD does not meet the legal definition of a dietary supplement, nor is it an approved food additive or generally recognized as safe (GRAS) for use in regular food.

Dietary supplements are special types of food in which stricter production controls have been mandated because not all ingredients are required to be approved additives, generally recognized as safe, or conventional food ingredients. Active or primary ingredients in dietary supplements have known physical effects on the body beyond ordinary growth and maintenance of healthy bodily functions—some of which may be new to the United States. Their active ingredient inclusion into regular food would diminish certainty that their use in regular food would not be harmful under intended, common or usual conditions. In these situations, ingredients outside what is normally allowed in regular food are regulated as either dietary supplements or possibly new drugs.

Industrial hemp is legally defined in Montana law under the Alternative Agricultural Crops Act, which states that industrial hemp “means all parts and varieties of the plant *Cannabis sativa* L. containing no greater than 0.3% tetrahydrocannabinol” for the dry weight of the crop. The term is also defined in federal law in Section 7606 (b)(2) of the Agricultural Act of 2014, commonly known as the “Farm Bill” (Public Law 113-79).

FDA has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce, any food, including any animal food or feed, to which THC or CBD has been added, regardless of the source.

Therefore, use of industrial hemp as the source of THC or CBD to be added to food products is prohibited. Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as food, CBD products are not an approved food, food ingredient, food additive, or dietary supplement.

### **Policy**

Food operators need to prove the applicable provisions below are being complied with during the pre-licensing and post-licensing inspection processes regarding approved food ingredient sourcing and non-adulteration status:

1. Source and non-adulteration status can be verified by providing the inspecting sanitarian with written documents that show the origin of the industrial hemp is from a verifiable and legal source. Participation in legally-allowed industrial hemp program would aid in this verification step. The Montana Department of Agriculture is one example of an agency that operates a legally-allowed industrial hemp program. If a food operator can prove they are a participant in such a program, this would provide a firm foundation upon which to conclude the foodgrade industrial hemp seed and industrial hemp seed oil is from an approved source.
2. Verifiable foodgrade industrial hemp seeds and industrial hemp seed oil will be allowed in food and dietary supplements, if and only if, the food is marketed without any and all health and health-related claims. If health or health-related claims are made for such products, the product in question will be regulated as an unapproved drug, rather than food.
3. Hemp-related ingredients that will not be allowed in food:
  - a. Any and all CBD products derived from cannabis plants; and
  - b. Any and all CBD products, including CBD oil, derived from industrial hemp; and
  - c. Hemp oil that is not derived from industrial hemp seeds; and
  - d. Industrial hemp seed oil with *added* CBD or other cannabinoids.
4. Prepackaged CBD products manufactured outside Montana that are already in commerce:
  - a. CBD products marketed only as botanical substances, not as food, and do not make any health or health-related claims, should not be considered a workload obligation for the local health authority for possible enforcement action;
  - b. CBD products marketed as food and make any health or health-related claims, should be considered a workload obligation for the local health authority for enforcement actions under the Montana Food, Drug and Cosmetic Act. Local health authorities are encouraged to work with their local law enforcement authorities and county attorney to decide whether to create and implement an enforcement plan.
5. Operators who propose to manufacture CBD products within Montana should be referred to the Montana Department of Agriculture Industrial Hemp Pilot Program to discuss options and legal status.
6. If there is probable cause to believe a food or dietary supplement in commerce, or is intended for introduction into commerce, may contain suspected illegal levels of THC or CBD, the sanitarian or authorized agent should contact their supervisor to decide whether to procure a sample for testing under provisions allowed under the Montana Food, Drug and Cosmetic Act. Local health authorities are encouraged to work with their local law enforcement authorities and county attorney to decide whether to create and implement an enforcement plan.